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PUBLIC VERSION - REDACTED

VIA ELECTRONIC FILING

Honorable Dennis M. Cavanaugh, U.S.D.J.
United States District Court
U.S. P.O and Courthouse, Room 451
Federal Square
P.O. Box 99
Newark, NJ 07101-0999

Re: *Eli Lilly and Company v. Actavis Elizabeth LLC et al.*,
Civil Action No. 07-3770 (DMC)(MF) (D.N.J.)

Dear Judge Cavanaugh,

We, along with our co-counsel Alston & Bird LLP, represent Defendant Mylan Pharmaceuticals Inc. ("Mylan") in the above matter. We recognize that ordinarily no reply brief is authorized under Local Civil Rule 7.1(d)(3) in connection with Mylan's pending Motion to Reconsider the Court's August 18, 2010 Order as it relates to Plaintiff Lilly posting security in the amount of \$10 million. However, Mylan respectfully submits this letter brief in lieu of a more formal brief as a result of two recent events, which Lilly had the benefit of addressing in its papers but which Mylan did not because (i) the Federal Circuit's grant of injunction pending appeal did not occur until the submission of Mylan's papers, and (ii) Mylan was not informed of final FDA approval of other ANDAs for atomoxetine hydrochloride until after such submission.

In light of the unique setting of this application, the emergent appeal that is pending, and for the reasons set forth herein, it is respectfully requested that Your Honor accept this letter brief for consideration at this time.

I. Lilly Inaccurately (And Inconsistently) Asserts That Mylan's Request For Reconsideration Is Moot

Lilly contends that Mylan's request for reconsideration is moot because the Federal Circuit determined that Mylan and the other defendants were not entitled to an increased bond when that court granted Lilly's motion for an injunction pending appeal. This is not so. That the Federal Circuit did not require Lilly to post additional security in its order granting an injunction pending appeal has no bearing on whether an increased bond is appropriate here. In fact, the Federal Circuit's August 31 order *did not deny* Mylan's and the other defendants' request for a bond, as Lilly suggests, but rather the Order is simply silent as to the defendants' request in this

Honorable Dennis M. Cavanaugh, U.S.D.J.

September 7, 2010

Page 2

regard. *See* Exhibit 1 (August 31, 2010 Order from the U.S. Court of Appeals for the Federal Circuit, Case No. 2010-1500). Further, the supposed “obvious reasons” that Lilly asserts for the Federal Circuit not imposing an additional bond are mere conjecture and wholly lacking support.

Moreover, after Lilly submitted its opposition brief, Mylan and several of the other defendants submitted a motion to the Federal Circuit requesting that the matter of increasing the security presently posted by Lilly be remanded to this Court in light of the recently granted injunction through appeal. *See* Exhibit 2 (Defendants-Appellees’ Motion for Remand, No. 2010-1500, without exhibits). Indeed, the defendants seek the opportunity to petition this Court for an increased bond for many of the same reasons asserted in support of Mylan’s Motion for Reconsideration.¹

Remarkably, Lilly has asked this Court to disregard the merits of Mylan’s Motion. Yet, on September 3, 2010, Lilly nonetheless asserted that the Federal Circuit should deny Mylan and the other defendants’ motion for remand to increase the security bond because “*Mylan’s request is already pending before the district court.*” *See* Exhibit 3 at 1 (Lilly Opposition to Motion for Remand, No. 2010-1500) (emphasis added). Lilly should not be permitted to say one thing in one courthouse and the *exact opposite thing* before this Court.

Having represented to the Federal Circuit that the district court will be addressing Mylan’s Motion for reconsideration of the bond amount on the merits, this Court should not countenance Lilly seeking to dismiss Mylan’s Motion as “moot” before this Court. Indeed, in light of Lilly’s two-courthouse approach, it is black letter law that Lilly is judicially estopped from doing so. *See Lincoln v. Momentum Systems, Ltd.*, 86 F. Supp. 2d 421, 427 (D.N.J. 2000) (“Judicial estoppel is a judge-made doctrine that seeks to prevent a litigation from asserting a position inconsistent with one that he or she has previously asserted in the same or previous proceeding.”); *Marino v. Adamar of Jersey, Inc.*, No. 05-4528 (RMB), 2009 WL 260799 at *3 (D.N.J. Feb. 4, 2009) (noting judicial estoppel is “designed to prevent a litigant from playing ‘fast and loose’ with the Court”).

II. In Asserting That The Harm Underlying Mylan’s Request For Reconsideration is Based On Speculation, Lilly Overlooks An Important Distinction Regarding Final FDA Approval

Lilly asserts that the harm asserted by Mylan in support of an increased bond is speculative, in part, because other defendants’ have received final FDA approval of their

¹ While this Court may be inclined to believe that Mylan’s instant Motion will be duplicative of any subsequent motion brought by the defendants for an increased bond, we respectfully submit that Mylan’s Motion should be treated separately because Mylan cannot foresee whether the Federal Circuit will grant its request for a limited remand. Even if the Federal Circuit remanded the issue of increasing the bond amount, Mylan’s damages, which exceed \$10 million for the fourteen-day injunction period, will be relevant to the Court’s consideration of an appropriate bond amount for a prolonged injunction.

Honorable Dennis M. Cavanaugh, U.S.D.J.

September 7, 2010

Page 3

ANDAs. However, that it has now become apparent that other defendants have received final approval of their ANDAs for atomoxetine hydrochloride capsules, in addition to Mylan, does not detract from the increased bond Mylan seeks.

As noted in Mylan's Motion, the actual losses to Mylan within the first fourteen days of generic entry are many tens of millions of dollars greater than the \$10 million presently posted by Lilly. This is because, as the first generic entrant into the market, Mylan would enjoy an initial surge in sales, as retailers and wholesalers and other customers would have desired to build up inventories of Mylan's product. The income Mylan could have received, if it were not enjoined from launching its atomoxetine products, [REDACTED]

[REDACTED] This value is not based on speculation, as Lilly suggests, but rather was derived from anticipated customer requirements for generic atomoxetine capsules, derived from communications with potential customers, market data and research, commercially prepared quantities and historical experiences. *See* Second Declaration of Tony Mauro, ¶ 6 (D.E. 696-1).

Lilly must post a bond that is at least equal to the amount that Mylan can reasonably expect for payment of "the costs and damages sustained by any party found to have been wrongfully enjoined." *See* FED. R. CIV. P. 65(c). Therefore, the bond amount should be set at a high enough level that it can potentially remunerate Mylan if the most "conservative" assumptions are realized at the time damages are actually assessed. In the present circumstances, it would be appropriate to base a bond on a best case scenario in which Mylan is the sole generic product on the market through the interim period. Furthermore, final approval means an applicant's ANDA has met the FDA's regulatory requirements. That an ANDA applicant has received final approval says nothing as to the applicant's capacity or willingness to launch at risk at the time final approval is received. [REDACTED]

[REDACTED] (*see* Second Declaration of Tony Mauro, ¶ 6 (D.E. 696-1)), Lilly provides absolutely no information establishing that any other defendant could do the same then or at the time they received final approval. This important distinction, overlooked by Lilly, shows that the harm asserted by Mylan is not overshadowed by "significant doubt."

Inasmuch as Lilly can be expected to argue that Mylan's recovery should be limited to the security posted by Lilly (the merits of which Mylan would dispute), it is critical that this Court impose a security that is consistent with Mylan's actual damages over the fourteen-day injunction period. *See Mead*, 201 F.3d at 888 ("When setting the amount of security, district courts should err on the high side..."). To allow Lilly to benefit from injunctive relief, without posting an appropriate security, frustrates the purpose of Federal Rule of Civil Procedure 65(c).

III. Mylan's Request for Reconsideration is Timely

Mylan could not have known that the Court would impose a two-week injunction, yet Lilly argues that Mylan should have presented evidence in that regard in its opposition papers. Following Lilly's logic, Mylan should have presented evidence regarding every possible time-

Honorable Dennis M. Cavanaugh, U.S.D.J.

September 7, 2010

Page 4

period for which the Court *could have* granted an injunction. No one is expected to bear such a heavy burden in opposing an adversary's request for injunctive relief and Mylan could not have been expected to do so here. Indeed, courts have recognized that a motion for an injunction and response papers are typically devoted to the merits of the request for the injunction and a reasonable litigant would not expect the court to require all evidence regarding the bond amount at that time. *See, e.g., Mead Johnson & Company v. Abbott Laboratories*, 201 F.3d 883, 887 (7th Cir. 2000) (noting that "a litigant naturally would suppose (in the absence of notice) that a hearing on a request for a preliminary injunction will be devoted to the merits of that request, rather than to fixing the amount of the bond").

The fact that Mylan was unaware and had no way of knowing that the Court would impose a two-week injunction satisfies the requirement that new evidence must have been unknown or unavailable to the plaintiff at the time the injunction was being considered in order to be submitted on a motion to reconsider. *See Okagbue-Ojekwe v. Federal Bureau of Prison*, No. 03-2035(NLH), 2007 WL 4591374, at *2 (D.N.J. Dec. 26, 2007) (stating that the statement in plaintiff's affidavit that he was unaware of evidence at the time of motion to dismiss satisfied the requirement that new evidence must have been unknown or unavailable).

In addition, Lilly's reliance on *Fellenz v. Lombard Investment Corp.*, 400 F. Supp. 2d 681 (D.N.J. 2005) and *Bowers v. NCAA*, 130 F. Supp. 2d 610 (D.N.J. 2001) is inapposite. Neither *Fellenz* nor *Bowers* address the specific issue of whether a litigant may submit additional evidence on a motion to reconsider under Local Civil Rule 7.1(i) where the movant was unaware of the evidence or unable to present the evidence until after the order at issue had been entered. Therefore, both cases are inapplicable here.

IV. Lilly Does Not Contest That An Increased Bond Is Warranted

Notably, Lilly does not dispute that an increased bond is warranted here. Lilly instead makes ancillary arguments—asserting Mylan's Motion is moot and untimely and the amount of bond Mylan seeks is speculative. This is because Lilly agrees that it should be held liable for posting an appropriate bond. Indeed, in requesting injunctive relief from this Court, Lilly stated that it "will post an appropriate bond or other security acceptable to the Court to protect Defendants from any damages they may suffer should the injunction be found to have been improvidently issued pending resolution of the disputed issues on appeal." (D.E. 662 at 3) Even in its papers submitted to the Federal Circuit, Lilly asserted that a \$60 million undertaking would be suitable for injunction through appeal. *See Exhibit 4 at 9* (Lilly's Reply in support of motion for injunction, No. 2010-1500). An increased bond that corresponds to the damages Mylan will suffer is appropriate, as even Lilly admits.

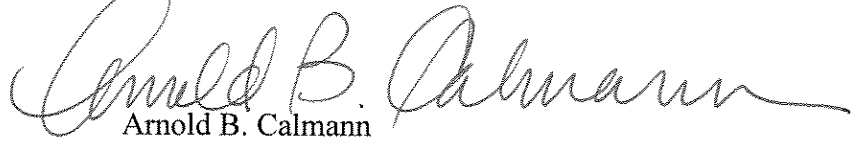
We very much appreciate Your Honor's indulgence and respectfully request that the Court accept this letter brief in considering Mylan's application.

Honorable Dennis M. Cavanaugh, U.S.D.J.

September 7, 2010

Page 5

Respectfully submitted,

A handwritten signature in cursive script, reading "Arnold B. Calmann". The signature is written in black ink and is positioned above the printed name.

Arnold B. Calmann

cc: All Counsel of Record (via email)